FEB 0 8 2013

510 K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k123799

Submitted By: Psychemedics Corporation

5832 Uplander Way
Culver City, CA 90230
TEL: 310 216 7776
FAX: 310 216 6662

Submission Contact: Virginia Hill

Date Prepared: December 7, 2012

Device Trade Name: Psychemedics Microplate EIA for Oxycodone in Hair

Predicate Device: RapidOne-OXY Test, k014101

Product Code: DJG

Device Classification/Name: 21 CFR 862.3650, Enzyme Immunoassay, Opiates; Classification II;

Intended Use: The Psychemedics Microplate EIA for Oxycodone is an enzyme immunoassay (EIA) for the preliminary qualitative detection of the opiate oxycodone in human head and body hair using an oxycodone calibrator at 2 ng /10 mg hair cutoff for the purpose of identifying oxycodone use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone.

The Psychemedics Microplate EIA oxycodone assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS or LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Assay Description: The test consists of two parts; a **pre-analytical** hair treatment procedure (to convert the solid matrix of hair to a measurable liquid matrix) and the **screening assay**, the Psychemedics Microplate EIA for Oxycodone. The drug is recovered from the hair using a patented method (U.S. Patent #8,084,215).The screening portion of the test system consists of (1) microplate

wells coated with multiple drugs including oxycodone conjugated to bovine serum albumin (BSA) (patent pending), polyclonal rabbit anti-oxycodone, goat anti-rabbit secondary antibody conjugated to HRP (horseradish peroxidase), substrate [3, 3', 5, 5' tetramethylbenzidine (TMB)], HCl to acidify (which stops the reaction), and wash buffer for washing the plates. Absorbance in the wells is read with a microplate reader.

Sample Collection:

A sample of hair should be cut as close as possible to the skin. The hair is placed in a V-shaped aluminum foil sample holder with the root end of the hair protruding beyond the slanted edge of the foil. The aluminum foil is crimped around the sample, securing the hair specimen firmly into place within the foil. The hair sample, crimped within the foil, is placed in a sample acquisition card envelope and the envelope is sealed with a tamper-evident seal. Hair specimens are kept at ambient temperature in a secure location until they are shipped without refrigeration to the laboratory.

Materials required:

Hair sample collection kit, Microplate EIA for Opiates, Microplate washer and reader, LC/MS/MS for confirmation.

Comparison with Predicate:

Item	Proposed Device	RapidOne-OXY Test K014101
Indications/ Intended use	The Psychemedics Microplate EIA for Oxycodone is an enzyme immunoassay (EIA) for the preliminary qualitative detection of the opiate oxycodone in human head and body hair using an oxycodone calibrator at 2 ng /10 mg hair cutoff for the purpose of identifying oxycodone use. The Psychemedics Microplate EIA oxycodone assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS or LC/MS/MS) is the preferred confirmatory method.	RapidOne OXY Test is a one-step, lateral flow immune-assay for the detection of oxycodone in urine. It is intended for qualitative detection of oxycodone in human urine at 100 ng/mL. RapidOne OXY Test is intended for professional use. It is not intended for over-the-counter sales to non-professionals. It provides only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result. GC/MS is the preferred confirmatory method.
Product Code	DJG	DJG

Measurand	Oxycodone in Hair	Oxycodone in Urine
Test System	Psychemedics EIA for Oxycodone in Hair	American Bio Medica Corp. "RapidOne-OXY" Test
Sample Matrix	Hair	Urine
Method of Measurement	Microplate reader, read at 450 nm	Lateral Flow immunoassay, visually read endpoint
Cutoff	2 ng oxycodone/10 mg hair (200 pg oxycodone/mg hair)	100 ng oxycodone/mL urine
Type of Test	Enzyme Immunoassay	Immunoassay
Extraction Method	Patented Digestion method	Not applicable
Confirmation Method	LC/MS/MS	GC/MS

Summary of Performance Testing

The precision studies were performed by spiking negative hair with previously LC/MS/MS-validated calibrator and control spiking solutions to achieve concentrations of negative, the cutoff of 2 ng/10 mg hair, and +/-75%, +/-50%, and +/- 25% of the cutoff.

Precision Studies

Summary -Intra-Assay		
LEVEL	NEG	POS
B_0 (-100%)	15	0
-75%	15	0
-50%	15	0
-25%	15	0
plus 25%	0	15
plus 50%	0	15
plus 75%	0	15
plus 100%	0	15

Summary-Inter-Assay		
LEVEL	NEG	POS
B_0 (-100%)	75	0
-75%	75	0
-50%	75	0
-25%	75	0
plus 25%	0	75
plus 50%	0	75
plus 75%	0	75
plus 100%	0	75

Agreement Testing

One hundred sixty one samples were confirmed by LC/MS/MS in parallel with testing by the Psychemedics Oxycodone EIA, with the results shown in the following table.

LC/MS/MS-Oxycodone Equivalents:	**Negative (< -10% of Cutoff)**	**≥10% and < -50% of Cutoff**	**≥ -50% and < Cutoff**	**≥ Cutoff, and < +50% of cutoff**	**≥ +50% and < +100% of cutoff**	**≥ +100% of cutoff**
EIA Positive	0	0	7	8	2	87
EIA Negative	47	4	6	0	0	0

The studies comparing the EIA with LC/MS/MS comprised the following: subjects ranging in age from 19 to 67 years; 92 males and 69 females; 82 black hair samples, 74 brown (from light brown to dark brown), and 5 grey or "salt & pepper;" 79 Caucasian subjects, 24 African-American, 34 Hispanic, and 24 Asian; 134 head hair samples, 27 body hair.

Discordant Results of Comparison Testing

Sample #	Cutoff Value (ng/10 mg hair)	Candidate Device (+/-)	LC/MS/MS (ng oxycodone-equivalents/ 10 mg hair)
3	2	POS	1.16
5	2	POS	1.28
10	2	POS	1.46
12	2	POS	1.78
13	2	POS	1.95
14	2	POS	1.95
15	2	POS	1.96

All of the discrepant results were positive in the immunoassay but fell below the cutoff by LC/MS/MS analysis. This is expected, as the samples are not washed for the screening assay, whereas once determined to be presumptive positive in the screening assay, second aliquots of the samples are weighed and washed extensively by our published wash procedures prior to digestion and extraction for LC/MS/MS

Cosmetic Treatments

Twenty opiate-negative hair samples were treated with bleach, 20 with permanent wave, 20 with dye, 20 with relaxer, and 20 with shampoo, and the results compared to the same samples without the treatments. In each case of the 20 samples treated with a type of cosmetic treatment, 10 samples were treated with one brand of a particular product and 10 other samples with a second brand. No significant differences in EIA results were observed for the negative hair samples before and after the treatments; all samples remained negative after the treatments. Samples were confirmed by LC/MS/MS prior to the treatments.

Twelve to sixteen oxycodone-positive hair samples were treated with bleach, permanent wave, dye, relaxer, and shampoo, and the results compared to the same samples without the treatments. In each case of samples treated with a type of cosmetic treatment, 6 – 8 samples were treated with one brand of a particular product and 6 – 8 samples with a second brand. None of the samples became negative, by either EIA or LC/MS/MS, after treatment with any of the cosmetic products.

<u>The Wash Procedure and Confirmation by LC/MS/MS</u>

<u>Wash procedure</u>

i. Add 2 mL of dry isopropanol and shake in waterbath for 15 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove isopropanol.
ii. Add 2 mL of Wash Buffer (0.01 M phosphate buffer, pH 6.0; containing 0.1% BSA) and shake in waterbath for 30 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
iii. Repeat Step ii. two more times.
iv. Add 2 mL of Wash Buffer, and shake in waterbath for 60minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.

v. Repeat Step iv. one more time. Hair sample is now ready for digestin and extraction for LC/MS/MS confirmation.

Confirmation

After washing the hair is digested with dithiothreitol and proteinase K for 6 hours. The digestion supernatant is extracted and confirmed by LC/MS/MS for opiates, including oxycodone.

Summary of Cross-reactivity and Interference Studies

Two compounds, oxymorphone and hydrocodone, showed significant cross-reactivity in the Opiate EIA assay. One-hundred-thirty-eight other compounds showed no cross-reactivity in the assay. One-hundred-sixteen compounds tested for interference at +/-50% of the cutoff showed no interference in the assay.

Cross-reactivity of related Compounds in Oxycodone EIA

Sample/Test Compound	% Cross-reactivity	Expected Concentration at 2ng Oxycodone/10 mg hair Cutoff
Oxymorphone	100	2
Hydrocodone	7.7	26
Hydromorphone	0.2	1000
Codeine	< 0.2	>1000
Acetylcodeine	< 0.2	>1000
6-Acetylmorphine	< 0.2	>1000
Morphine	< 0.2	>1000
Propoxyphene	< 0.2	>1000
Methadone	< 0.2	>1000
Dihydrocodeine	< 0.2	>1000
Ethylmorphine	< 0.2	>1000
Dihydromorphine	< 0.2	>1000
Naloxone	< 0.2	>1000
Naltrexone	< 0.2	>1000
Nalorphine	< 0.2	>1000
Propoxyphene	< 0.2	>1000
Morphine Glucuronide	< 0.2	>1000
Meperidine	< 0.2	>1000
Dihydrocodeine	< 0.2	>1000

Environmental Contamination

Contamination of hair by soaking in 500 ng oxycodone /mL of water resulted in a range of oxycodone on the hair of 0.8 to 20.9 ng of oxycodone /10 mg hair before washing. After washing by the procedure described above, all samples were negative, with the amount of oxycodone remaining on the hair samples ranging from 0.05 to 0.94 ng/10 mg hair.

Contamination of hair by soaking in 500 ng oxycodone /mL of saline resulted in a range of oxycodone on the hair of 0.7 to 2.5 ng of oxycodone /10 mg hair before washing. After washing by the procedure described above, all samples were negative, with the

amount of oxycodone remaining on the hair samples ranging from 0.11 to 0.42 ng/10 mg hair.

Stability of Calibrator and Control Solutions

The oxycodone calibrator and control solutions are prepared in-house by the laboratory from certified standards. Stability of the oxycodone calibrator and control solutions was shown to be 6 months, with ongoing studies to demonstrate 1-year stability.

Recovery

Recovery of oxycodone from hair in a 2-hour incubation averaged 89%.

Conclusion:

Comparison of results of the Psychemedics Microplate EIA for Oxycodone in Hair with LC/MS/MS confirmation showed the results to be substantially equivalent. The Psychemedics Microplate EIA for Oxycodone in Hair is substantially equivalent to the predicate, based on acceptable performance studies, including precision, specificity, interference (including cosmetic effects), and removal of external contamination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 8, 2013

Psychemedics Corporation
c/o Ms. Virginia Hill
5832 Uplander Way
Culver City, CA 90230

Re: k123799
Trade/Device Name: Psychemedics Microplate EIA for Oxycodone in Hair
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG
Dated: January 11, 2013
Received: January 17, 2013

Dear Ms. Hill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director,
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123799

Device Name: Psychemedics Microplate EIA for Oxycodone in Hair

Indications for Use:

The Psychemedics Microplate EIA for Oxycodone is an enzyme immunoassay (EIA) for the preliminary qualitative detection of oxycodone in human head and body hair using a oxycodone calibrator at 2 ng /10 mg hair cutoff for the purpose of identifying oxycodone use. This is an in vitro diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone.

The Psychemedics Microplate EIA oxycodone assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS or LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Psychemedics plans to perform this test at one site. Psychemedics has not performed an evaluation of reproducibility at different sites.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.02.05 14:46:03 -05'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k)_____k123799_____